REMARKS

Applicant respectfully requests entry of the amendments presented herein. Claim 14 has been amended to correct a typographical error. In addition, numerous amendments to the specification have also been presented herein. These amendments are also presented in order to correct several typographical errors and other matters of form in the specification. None of the amendments presented herein adds new matter to the application. In addition, Applicant has submitted concurrently with this paper a set of corrected drawings, including marked-up copies of the original drawings and a separate letter requesting entry of the proposed drawings amendments.

It is believed that the claims are patentable in their present form, and a prompt notice of allowance for this case is respectfully requested. If the Examiner finds any remaining impediment to the prompt allowance of this application, please contact the undersigned attorney.

DATED this 27TH day of MARCH 2003.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE:

IN THE SPECIFICATION:

Paragraph beginning at line 6 of page 39 has been amended as follows:

To optimally position intraluminally directed anvil apparatus 200 ~~100~~, catheter system 100 is utilized as shown in FIG. 1 and FIGS. 2A-2F. FIG. 1 depicts a patient undergoing the initial step of a procedure utilized to remotely position the intraluminally directed anvil apparatus 200 at an anastomosis site 10 in a blood vessel 20 (not shown in FIG. 1) in the chest or arm such as the brachial artery from a catheterization site 40 in a blood vessel in the patient's leg, the femoral artery. Catheter system 100 is shown in FIG. 1 with an introducer 110 inserted at catheterization site 40 in the femoral artery. Introducer 110 permits a guide wire 120 to be inserted to the anastomosis site. Guide wire 120 preferably utilizes a coil 125 to minimize the potential of the guide wire 120 to cause damage. Guide wire 120 typically follows a fluoroscopic device, an endoscopic device or some other remote viewing instrumentation or imaging technique used to determine the location for the anastomosis site 10 such as the proximity of a blood vessel occlusion or another abnormality that has been detected by a conventional exploration technique. Any conventional guide wire suited for inserting both diagnostic and therapeutic catheters may be utilized such as those disclosed in U.S. Pat. No. 4,846,186, which is hereby incorporated by reference in its entirety, and catheters and guide wires for vascular and interventional radiology are disclosed in *Catheters, Methods, and Injectors*, at 155-174, which is also hereby incorporated by reference in its entirety.

Paragraph beginning at line 24 of page 39 has been amended as follows:

Hub 115 is shown ~~shows~~ at the proximal end of guide wire 120 in FIG. 1. The proximal end of a catheter system such as catheter system 100 comprises one or a plurality of access ports or luer fittings such as hub 115. For the purpose of simplicity, the proximal end of the various catheters depicted in FIG. 2A-2E are not shown. However, the manufacture and handling of a catheter system with a plurality of lumens and a plurality of access ports are known to those of ordinary skill in the art. For example, U.S. Pat. Nos. 5,662,580 and 5,616,114, which have herein been incorporated by reference in their entirety, disclose catheters with a plurality of access ports or luer fittings and a plurality of lumens.

Paragraph beginning at line 16 of page 40 has been amended as follows:

FIG. 2B depicts the next phase of utilizing catheter system 100. Positioning catheter 140 is designed to have an inherent curvature or curved memory at its distal end. In order to enable positioning catheter 140 to be moved as needed while moving through the patient's body to the anastomosis site, straightening catheter 130 extends within positioning catheter 140 ~~130~~ in order to straighten positioning catheter 140. Guide wire 120 also assists in providing resistance to the inclination of the distal end of the positioning catheter 140 ~~130~~ to curve. Once anastomosis site 10 has been reached and the guide wire 120 has been removed, then catheter system 100 appears as shown in FIG. 2A. The straightening catheter 130 is then withdrawn as shown in FIG. 2B, to permit the distal end of the positioning catheter 140 to curve against the wall of blood vessel. An arrow is shown in FIG. 2B to indicate that a penetration catheter 150 containing a penetration wire 160 is inserted into straightening catheter 130 ~~140~~. The

straightening catheter can be removed at this point as indicated by the arrow in FIG. 2B ~~2b~~ or it can remain.

Paragraph beginning at line 9 of page 41 has been amended as follows:

FIG. 2D depicts catheter system 100 once positioning catheter 140 ~~130~~ and straightening catheter 130 ~~140~~ have been removed from around penetration catheter 150 and once penetration wire 160 has been removed from within penetration catheter 150 ~~160~~. At this point, penetration catheter 150 extends from catheterization site 40 (not shown in FIG. 2D) to anastomosis site 10 through the wall of blood vessel 20 at initial piercing 15. Catheter system 100, more particularly, penetration catheter 150 of catheter system 100 can then be used in association with the intraluminally directed anvil anastomosis apparatus 200.

Paragraph beginning at line 10 of page 42 has been amended as follows:

In another embodiment of an anvil apparatus 200' described below in reference to FIG. 9, the anvil apparatus may be positioned through the use of a catheter system that comprises only a single catheter such as positioning catheter 140. Since anvil apparatus 200' is positioned at an anastomosis site by passing through a catheter such as positioning catheter 140, it is necessary for the catheter to have dimensions that accommodate the diameter or width of the anvil to be inserted. In some of the experiments performed in the context of this invention, a catheter characterized as a 13 French sheath, also known as a 4.3 mm catheter C1 French unit = 1/3 mmC, has been found suitable for most anvil apparatus insertions. Catheterization techniques are described, for example, by Constantin Cope and Stanley Baum, *Catheters, Methods, and*

Injectors for Superselective Catheterization, in *Abrams' Angiography*, edited by Stanley Baum, 4th ed., (this work will hereinafter be referred to as "*Catheters, Methods, and Injectors*") which is hereby incorporated by reference in its entirety. However, as described above, it is preferable to utilize an anvil apparatus such as anvil apparatus 200 and to position the anvil against the wall of the blood vessel by pulling the anvil pull 230 after it has been inserted into a penetration catheter 150 ~~160~~. Penetration catheter need only be a 5 French sheath to receive the anvil pull 230 of most anvil apparatus.

Paragraph beginning at line 13 of page 43 has been amended as follows:

Anvil 210 and anvil pull 230 are preferably fixedly attached together. As shown, anvil pull 230 extends through anvil 210 via an anvil aperture 216 (not shown) and terminates at a stopping element 236. Since the anvil pull is typically metal and the anvil is typically molded plastic, stopping element 236 may be just the proximal end of anvil pull 230 embedded in anvil 210 such that it is still visible. Of course, the proximal end may be embedded in a way such that it is not visible as shown in FIG. 9B. In the embodiment shown in FIG. 2F, the stopping element 236 is the proximal end of anvil pull 230 that has been bent so that it is partially embedded in terminal end 218 of anvil 210. As described below, anvil 210 and anvil pull 230 may also be integral. Additionally, anvil 210 may be movably positioned on anvil pull 230 in which case, stopping element 236 ~~23~~ can be used to brace against terminal end 218 of anvil 210.

Paragraph beginning at line 24 of page 43 has been amended as follows:

After the anvil 210 has been positioned such that its engaging end 212 contacts the intima

of vessel 20 with anvil pull 230 ~~210~~ extending through the wall of vessel 20, then anvil apparatus is ready to be utilized in an anastomosis procedure for joining vessel 20 with another vessel such as graft vessel 50 which may be any synthetic graft vessel such as ePTFE tubular grafts. Numerous approaches are disclosed herein for joining a portion of a first vessel that define a first vessel opening to a portion of a second vessel that defines a second vessel opening such that the first vessel and the second vessel are anastomosed together and are in fluid communication. A preferred approach involves the use of compression plates that provide for a desired degree of eversion of the vessels without requiring penetration of the vessels. An example of such compression plates is the guided compression plate apparatus shown in FIG. 3A. Guided compression plate apparatus 300 is described in greater detail under the section titled Compression plate apparatus.

Paragraph beginning at line 10 of page 44 has been amended as follows:

As can be seen from FIG. 3B, a graft vessel 50 is loaded onto holding tabs 314b of compression plate 310b ~~314~~ while a cutter 400 is positioned to be loaded into the lumen 58 of graft vessel 50. Cutter 400 includes a cutting tube 410 that terminates at a cutting knife 412 with a cutting edge 414. Note that a variety of cutters are disclosed herein as discussed in the section entitled Cutting Devices. Once cutter 400 is positioned within graft vessel 50 as shown in FIG. 4C ~~3C~~, then the combination of compression plate apparatus 300, graft vessel 50 and cutter 400 are ready for use with anvil apparatus 200 to form an anastomosis. This combination is referred to herein as compression plate and cutter assembly 390 and is used much like a cartridge in the external anastomosis operator 700.

Paragraph beginning at line 9 of page 46 has been amended as follows:

There are significant advantages to combining vessels in accordance with the methodology described above especially in a manner such that there is at least partial eversion, contact between the everted surfaces and no penetration of the portions of the vessels defining the vessel openings. Of course, the anastomosis is fluid tight to normal systolic pressure and remains intact under stress. Since the everted portions 26 and 56 respectively cover the holding tabs 314a-b, no intraluminal foreign material is exposed and no subintimal connective tissue is intraluminally exposed. As a result, the thrombogenicity of the anastomoses is no greater than that of hand sutured anastomosis. Additionally, the configuration also results in an anastomosis that is morphologically satisfactory, including complete eversion of the receiving blood vessel intima with apposition to graft vessel. Further, everted portions 26 and <u>56</u> ~~56'~~ are in intima-intima contact and no cut portion is significantly exposed to the blood flow that is to circulate through the anastomosed structures.

Paragraph beginning at line 18 of page 48 has been amended as follows:

As shown in FIG. 6D, anvil pull 230 is inserted through cutter 400, through spring biasing device 450 and into an anvil pull holder 530. Holder knob 540 of anvil pull holder 530 is then rotated as described below to hold anvil pull 230. Once anvil pull holder <u>530</u> ~~230~~ securely holds anvil pull, then advancer knob 570 is rotated as shown in FIG. 6D. Rotation of advancer knob 570 causes anvil pull holder 530 to pull on anvil pull 230, which causes anvil pull 230 to advance within compression plate assembly 300 and distend the wall of vessel 20 until cutter 400 is engaged as depicted. Note that FIG. 4B depicts anvil 210 engaging cutter 400 at the same

point in the process as is shown in FIG. 6D except FIG. 4B does not show any of the components of external anastomosis operator being used.

Paragraph beginning at line 7 of page 50 has been amended as follows:

The anvil is preferably sized at its engaging end to have a greater cross-sectional area than a cross-sectional area defined by the perimeter of the cutting edge of the cutting device such that portions of the engaging end of the anvil extend beyond the cutting edge when the cutting device engages the anvil and forms the first vessel opening. This size differential is particularly useful for cutting when the cutting device is a mechanical cutter or knife as it permits the anastomosis fenestra or vessel opening to be formed through the action of the cutting edge 414 being ~~be~~ pressed against engaging end 212. This is a significant improvement over conventional cutting techniques that involve the external positioning of an anvil into the lumen of a vessel that is smaller than the cutter so that the vessel is cut as the cutter passes over the anvil. Such conventional cutting techniques operate much like a typical hand held paper punch used for forming holes by pushing a cutter over an anvil. Just like paper punches such vascular punches often fail to fully make the cut and leave a portion attached. The connective tissue in blood vessels in combination with the moist condition of the blood vessels further limit the effectiveness of such prior art cutting techniques. More particularly, cutting a moist highly interconnected material by squeezing it between the anvil and the cutter often results in part of the tissue merely slipping between the anvil and the cutter such that a portion is still attached.

Paragraph beginning at line 17 of page 51 has been amended as follows:

FIGS. 7A-7D provides examples for several embodiments of the anvil of this invention. A line 248 is a visual aid drawn through anvils 210a-d to clearly indicate that the portion of the anvil extending from line 248 to the anvil pull is the engaging end 212a-d. Engaging ends 212a-c ~~210a-e~~ are all spherical engaging ends like spherical engaging end 212 of anvil 210. Note that these spherical engaging ends are essentially a hemisphere at the side of the anvil proximal to the anvil pull 230. When the cutting device is cylindrical and is configured such that it permits part of the spherical engaging end of the anvil to be positioned in the chamber 420 then the cutter self centers on a spherical engaging end.

Paragraph beginning at line 25 of page 51 has been amended as follows:

Landing 214 of anvil 210 is also useful feature when the anvil is used in combination with a compression plate apparatus or some of the means for joining a portion of the first vessel that defines the first vessel opening to a portion of a second vessel that defines a second vessel opening such that the first vessel and the second vessel are anastomosed together and are in fluid communication. As noted above, landing 214 is essentially the surface of the cylindrical portion of anvil 210. When an anvil with a spherical engaging end and cylindrical landings such as anvil 210 is used with a compression plate apparatus such as apparatus 300 then the spherical engaging end can extend through first compression plate opening 320a and into the apparatus while landing 214 abuts the wall of blood vessel 20 against holding tabs 314a. The tolerance between landing 214 and holding tabs 314a is such that landing 214 initially rests against holding tabs 314a until sufficient force is applied to pull anvil 210 through compression plate apparatus 300. As shown in FIGS. 4B-4C and FIGS. 12D-12E, landing 214 assists in the eversion process

before anvil 210 is pulled through the compression plate apparatus. More particularly, landing 214 enables the portion 26 defining the first vessel opening 24 to be everted as everted portion 56 of graft vessel 50 is pushed against portion 26. As everted portion 56 pushes against portion 26, portion 26 curls up and over holding tabs 314a. This process preferably fully everts portion 26, however, satisfactory results are obtained even if portion 26 is only partially everted.

Paragraph beginning at line 21 of page 52 has been amended as follows:

FIG. 7C depicts an anvil 210c that has a spherical engaging end 212c ~~48~~ opposite from a tapered terminal end. As explained below, many features described herein in reference to an intraluminally positioned anvil apparatus also relate to an externally directed anvil apparatus. As shown in FIGS. 16A-16E, FIGS. 17A-17C, FIGS. 18A-18B, FIGS. 19A-19B, an anvil 210 may be inserted though a wall of a blood vessel at an insertion opening that has been selected as an anastomosis site and positioned in a lumen of the first vessel with the anvil pull 230 extending through the insertion opening of the blood vessel. Note that such use may require some modifications. For example, use of an anvil with a tapered end such as tapered end 218c minimizes the size needed for the insertion opening since the vessel wall can stretch as the taper of the anvil increases.

Paragraph beginning at line 14 of page 54 has been amended as follows:

Distal end 142' may be adapted for providing a lateral exit for piercing end 232' ~~232~~ of anvil pull 230' ~~230~~. Distal end 142' may have a deflecting surface and a lateral aperture that guides piercing end 232' ~~232~~ towards the intima of receiving blood vessel 20. Because piercing

end 232' ~~232~~ is very sharp, such deflecting surface is preferably a puncture and abrasion resistant surface. In addition, distal end 142' may have an appropriate marker for imaging the orientation of the aperture at distal end 142 and/or the position of distal end 142 itself. Such radio-opaque markers can be any of the radio-opaque markers known in the practice of angiography. Similarly, all of the catheters used in the anastomosis procedure may have radio-opaque portions. Anvil pull 230' is typically radio-opaque itself, although very thin embodiments of this wire are preferably coated with a material such as gold or a bio-compatible barium-containing substance to make them more visible. Catheter distal end configurations for directing outwardly an elongated member have been disclosed in U.S. Pat. Nos. 4,578,061, 4,861,336, 5,167,645, 5,342,394, and 5,800,450, which are hereby incorporated by reference in their entirety.

Paragraph beginning at line 1 of page 60 has been amended as follows:

Compression plates 310a-b are provided in the exemplary embodiment shown in FIG. 3A with a plurality of holding tabs 314a-b respectively protruding from opposing anastomosis sides 322a ~~(not shown)~~ and 322b of compression plates 310a-b. More particularly, holding tabs 314a-b extend respectively from rings 312a-b of compression plates 310a-b. Holding tabs 314a-b are intended to hold the everted contours of the structures being anastomosed. Each one of holding tabs 314a-b has a base that integrally extends from the anastomosis side of the ring 312a-b of the corresponding plate at 313a-b and that terminate at rounded tips 315a-b ~~316a-b~~. Distal tips 315a-b ~~316a-b~~ are preferably rounded as shown to minimize the potential for penetration. However, in some embodiments, the distal tips may be pointed, for example, when holding a graft vessel. Holding tabs 314a-b are typically rather rigid, however, they may also be designed to elastically

bend in such a way that the distal tips of such holding tabs slightly swing about their respective bases. Such a bending action may be caused by the displacement through any of openings 320a-b defined by holding tabs 314a-b, more particularly the distal tips 315a-b ~~316a-b~~ of holding tabs 314a-b.

Paragraph beginning at line 15 of page 60 has been amended as follows:

The number of holding tabs and their spacing may be varied as needed ~~need~~ as long as the portions of the vessels defining the vessel openings can be maintained in an everted orientation. For example, the plurality of holding tabs may include sixteen holding tabs as shown in FIG. 3A. However, smaller amounts may also be utilized, for example there may be only six to ten holding tabs.

Paragraph beginning at line 25 of page 60 has been amended as follows:

Each of the holding tabs shown in the embodiment ~~schematically~~ depicted in FIG. 3A ~~1~~ is attached at its base 316a-b at the inner peripheries 313a-b of rings 312a-b. However, the bases 316a-b may also extend from other locations of the rings. For example, the bases 316a-b may extend from rings 312a-b between the outer peripheries 311a-b and the inner peripheries 313a-b or perimeter on the anastomosis sides 322a-b of each annular compression plate.

Paragraph beginning at line 5 of page 61 has been amended as follows:

Although, it is not necessary for the holding tabs in each compression plate to be oriented relative to the holding tabs in the other compression plate in a mating configuration, it is preferred. When referring to the relative configuration of the holding tabs in opposing compression plates, the terms "mating or mated configuration" describe a configuration in which each one of the holding tabs in a compression plate can generally fit in the space between two neighboring holding tabs in the opposing compression plate when such compression plates are close enough. As shown by the phantom lines in FIG. 3A, holding tabs 314b are offset from holding tabs 314a such that as the plates are brought towards each other each holding tab 314b is positioned opposite from the spaces between holding tabs 314a in a mated configuration. When the compression plates are brought together just close enough for the tips 315a-b ~~316a-b~~ to be in the same plane, then the everted tissue is held in place and the anastomosis is secure. Failure to bring the compression plates sufficiently close together such that the tips 315a-b ~~316a-b~~ are significantly close together risks the potential loss of the tissue that has been captured and everted onto holding tabs 314a-b. Note that each holding tab 314b is shown just barely entering into an opposing space between adjacent holding tabs 314a. Of course, the compression plates may be designed for further compression such that holding tabs 314b further enter the space between adjacent holding tabs 314a. However, the compression plates are preferably designed such that the plates are brought together without penetrating blood vessel 20 or graft vessel 50. Note that guides 330 maintain the orientation of the compression plates so that the respective teeth have the preferred mating configuration.

Paragraph beginning at line 9 of page 65 has been amended as follows:

When second compression plate is formed from plastic, the desired frictional engagement is generally achieved whether guides 330 are made from metal or plastic. However, when

second compression plate is formed from metal and the guides are also metal, it is preferable to utilize an alternative frictional engagement. For example, FIG. 5A shows compression plate apparatus 300 with an optional holding ring 340 that has a friction coupling with guides 330 through its guide orifices 346. Holding ring 340 is provided with opening 348 whose internal diameter is preferably at least equal to that of the opening 320b ~~220b~~ of compression plate 310b. The frictional engagement of holding ring 340 with guides 330, like the frictional engagement described above for guide apertures 334 with guides 330, is such that expansion of the anastomosed structures cannot ~~can not~~ separate compression plates 310a-b with respect to each other when holding ring 340 is in contact engagement with exterior side 324b ~~(not shown)~~ of compression plate 310b opposite to its anastomosis side 322b. The holding ring may, for example, be formed from nylon.

Paragraph beginning at line 22 of page 65 has been amended as follows:

Other embodiments of this invention are provided with different frictional engagements that are designed to prevent compression plate 310b from significantly moving away from compression plate 310a. For example, guides 330" ~~330'~~ of compression plate apparatus 300" in FIG. 13 have barbs 336. These frictional engagement configurations described above enable the compression plates to be approached to a desired relative separation and maintained at that separation. This feature also permits the control of the pressure applied to the everted tissue of the anastomosed structures and the compression of the plates in stages so that they are approximated in a controlled manner.

Paragraph beginning at line 4 of page 66 has been amended as follows:

These frictional engagements are all examples of means for locking the compression plates together. More particularly, guides that engage appropriately sized apertures 334 of second compression plate 310b ~~plate 330b~~ for frictional engagement, a holding ring 340 that has guide orifices 346 sized to fractionally engage a guide 330, and guide barbs 336 for irreversible advancement of second compression plate 310b as the guide extends through guide apertures 334 of second compression plate 310b are all examples of means for locking the compression plates together. Note that when the frictional engagement is achieved through reliance on guides that extend from a first compression plate and that pass though appropriately sized apertures in the second compression plate then it can be said that the first compression plate and the second compression plate have means for locking the compression plates together. An advantage of such locking means that are part of the first and second compression plates is that it is not necessary to separately attach the locking means to the compression plate apparatus after it has been used to anastomose the vessels.

Paragraph beginning at line 19 of page 67 has been amended as follows:

First compression plate 310a' has a ring 312a' with an inner periphery 313a' ~~311'~~ and an outer periphery 311a' ~~313'~~. A plurality of holding tabs 314a' extend from ring 312a'. Like holding tabs 314a, each holding tab 314a' has a base 316a' and terminate at a distal rounded tip 315a'. The base of each tab is preferably integral, as shown, with ring 312a'. Each holding tab 314a' extends at its base from ring 312. More particularly, each holding tab 314a' extends from inner periphery 313a' ~~311'~~ from exterior side 324a' toward anastomosis side 322a' ~~(not shown)~~.

Paragraph beginning at line 25 of page 67 has been amended as follows:

Holding tabs 314a' extend either perpendicularly from ring 312a' of first compression plate 310a' or curve inward from exterior side 324a' of ring 312a' of first compression plate 310a' such that distal rounded tips 315a' ~~316a'~~ of holding tabs 314a' are perpendicularly oriented relative to exterior side 324a' ~~32a'~~ of ring 312a' of first compression plate 310a'. Like holding tabs 314a, holding tabs 314a' may have varying configurations and various numbers of holding tabs may be utilized.

Paragraph beginning at line 12 of page 71 has been amended as follows:

FIG. 12F depicts portion 26 fully everted on holding tab 314a' such that portion 27 opposite from rounded tip 315a' ~~316a'~~ is held in contact with the portion 57' of vessel 50 opposite from rim 368. After compression plate apparatus 300' has been compressed to join portion 26 of blood vessel 20 that defines first vessel opening 24 to portion 56' of second vessel 50' that defines graft vessel opening 54' then first vessel 20 and second vessel 50 are anastomosed together and are in fluid communication. Anvil apparatus 200 and cutter 400 have been removed upon the completion of the procedure through lumen 58 of graft vessel 50. More particularly, once the anastomosis is completed then anvil pull 230 is pulled so that it draws anvil 210 through openings 320a, 320b' and 372 of compression plate apparatus 300' such that anvil apparatus 200 is removed along with cutter 400 through lumen 58'. FIG. 12G depicts vessel 20 anastomosed to vessel 50' after attachment actuation device 600' has been removed.

Paragraph beginning at line 10 of page 74 has been amended as follows:

These cutting devices disclosed herein are all examples of cutting means for forming an opening in the wall of the first vessel at the anastomosis site through engagement with the anvil of an anvil apparatus as an engaging means holds the anvil pull of the anvil apparatus after receiving the anvil pull through the cutting means. The cutting devices engage an anvil to form the vessel opening in any suitable manner. For example, the cutting device may be pushed against the anvil, the anvil may be pulled against the cutting device, ~~cutter~~ or both may simultaneously occur such that the anvil is pulled as the cutting device ~~cutter~~ pushes against the anvil.

Paragraph beginning at line 3 of page 75 has been amended as follows:

It is not always necessary for cutter 400 to have a centering core or for other cutting devices to have a centering core or a centering conduit. When the engaging end of the anvil is spherical and the cutter is spherical and ~~is~~ configured such that it permits part of the spherical engaging end of the anvil to be positioned in cutter chamber 420 then the cutter self centers on the spherical engaging end. The entire cutting device need not be hollow. For example, cutting device 400'' has a recess 428 at its cutting end that is deep enough to permit the engaging end of anvil 200d' to extend into recess 428 so that anvil 200d' may be centered and seated. Accordingly, the cutting end is preferably adapted to receive a portion of the engaging end into the cutter to enable the engaging end to self center and be seated. Also, the engaging end is preferably convex and more preferably spherical.

Paragraph beginning at line 22 of page 75 has been amended as follows:

A spring-biased ~~spring-biased~~ cutter also enables the cutter to be pushed back by anvil 210 to allow anvil 210 to further distend the wall of vessel 20 as shown in FIGS. 4A-4B, FIGS. 6D□6E, FIGS. 12C-12E, FIGS 15B-15C and FIGS. 16D-16E. As anvil 210 pushes cutter 400 through vessel 20, anvil 210 causes cutter 400 to retract, however, increasing resistance is encountered as spring 460 becomes further compressed. So cutter 400 applies increasing amounts of pressure to vessel 20 as anvil 210 continues to stretch the wall of vessel 20 into compression plate apparatus 300. By optimizing features such as the tension of the spring and the length of the cutter, vessel 20 is distended far enough into compression plate apparatus 300 to leave sufficient lengths of the vessel in the compression plate apparatus for capturing in the subsequent eversion process onto holding tabs 314a. It has been found that about 17 -18lbs or about 20 lbs is generally required to form the anastomosis fenestra.

Paragraph beginning at line 7 of page 76 has been amended as follows:

The gradual increase in pressure also serves to assist a spherical engaging end 212 of anvil 210 to self center on cutter 400. If ~~Since the pressure increases gradually, if~~ anvil 210 is initially misaligned on cutter 400 then the gradual increase in pressure causes the anvil to be gradually drawn to center as the spherical engaging end 212 is pulled into chamber 420 or recess 428 of the cutting device. If pressure is applied too rapidly, the sharp cutting edge 414 of a cutter such as cutter 400 may dig into anvil 210 before anvil 210 can slide into a centered orientation. Accordingly, the use of a cutter with at least a recess at its cutting end and a spherical engaging end accommodates imperfections in the alignment of the cutter and the anvil.

Paragraph beginning at line 6 of page 77 has been amended as follows:

After the opening is formed by cutter 400' then the vessels may be joined in the same way that a vessel is joined perpendicularly to a side of another vessel. For example, the portions defining the openings may be clipped or stapled ~~staples~~ together through the use of a clipping or stapling device 800 that delivers clips 810 ~~800~~ or staples. If the vessels are mechanically joined through the use of sutures, staples or clips then it may be desirable to enhance the leak proof character of the anastomosis through the use of laser welding with a conventional laser welding device, such as an endoscopic laser welding devices. Similarly, the seal may be augmented through the appropriate use of biocompatible adhesives administered by conventional delivery devices, including endoscopic glue delivery devices. Additionally, a seal may be formed or strengthened by techniques such as laser soldering, including chromophore-enhanced laser soldering, and laser sealing.

Paragraph beginning at line 3 of page 81 has been amended as follows:

As indicated above, anvil pull engager 500 has two primary components including an anvil pull holder 530 and anvil pull advancer 560. Anvil pull holder 530 receives anvil pull 230 via spring biasing device 450. More particularly, anvil pull 230 extends through cutter cup 458, rotatable spring housing 456, spring 460 and sleeve 462 around spring 460, and out of threaded jam screw 464.

Paragraph beginning at line 8 of page 81 has been amended as follows:

Anvil pull holder 530 includes a holder mount 532 positioned in track 730 of body 710. In this embodiment, holder mount 532 is moveable so that the anvil pull can be advanced after it is held. However, in other embodiments, the anvil pull holder may just lock the anvil pull into position such that the cutter is moved against a stationary anvil. Similarly, the spring biasing device 450 may be eliminated so that the vessel is cut only by pressure exerted by the anvil pull against the cutter. As discussed above, while the cutter and the anvil may engage each other in these arrangements, it is preferable for the cutter to apply some pressure as the anvil pull is advanced against the cutter.

Paragraph beginning at line 16 of page 81 has been amended as follows:

Holder mount 532 may be utilized in different ways to hold anvil pull 230. Holder 530 has a split cone 534 inserted into a tapered chamber 536 against a spring 538. Anvil pull 230 extends through apertures in holder mount 532, spring 538, split cone 534 and out of an aperture centered in holder knob 540. Holder knob 540 is threadably engaged by holder mount 532 such that rotation of holder knob 540 advances split cone 534 in tapered chamber 536 causing split cone to lock onto anvil pull 230. ~~As shown in FIG. 6B, holder~~ Holder mount 532 may be ~~is~~ slotted at its distal end, as may ~~is~~ holder knob 540. By aligning the slot (not shown) ~~542~~ of holder knob 540 with the insert slot (not shown) ~~544~~ of holder mount 532, anvil pull 230 can be bent so that it extends through both the holder knob slot ~~542~~ and the insert slot ~~544~~. Holder ~~Then holder~~ knob 540 can then be rotated so that the bent portion of anvil pull 230 is rotated into one of the locking slots (not shown) ~~546a-b~~ that extend perpendicularly from the insert slot ~~544~~.

This securely locks anvil pull 230 into position. Anvil pull 230 can be locked through the use of slots instead of or in addition to the use of split cone 534 in tapered chamber 536.

Paragraph beginning at line 16 of page 82 has been amended as follows:

Since anvil pull holder 530 is moveable, it threadably engages rotatable lead screw 562 of anvil pull advancer. More particularly, lead screw 562 is threadably engaged by anti-backlash nut 550 which is fixedly attached to holder mount 532. Anti-backlash nut 550 has an attachment face 552 through which a plurality of attachment face screws 554 extend to hold holder mount 532 and anti-backlash nut 550 together.

Paragraph beginning at line 20 of page 83 has been amended as follows:

First plate engager 600a and second plate engager 600b each have a cutter aperture 620a and 620b, as shown in FIG. 6B. Cutter 400 extends through these aligned apertures 620a-b. First plate engager 600a is positioned on rail 640 such that it extends slightly beyond cutting edge 414 of cutter 400. This difference in length enables first compression plate 300a to be held slightly beyond cutter 400 in a manner that permits the wall of vessel 20 to be pulled into compression plate apparatus 300 as shown in FIG. 6D-6E and distended as needed.

IN THE CLAIMS:

Claim 14 has been amended as follows:

14. (Amended) A compression plate anastomosis apparatus as recited in claim 8 ~~1~~, wherein said guiding means extend from the first compression plate with a perpendicular orientation.

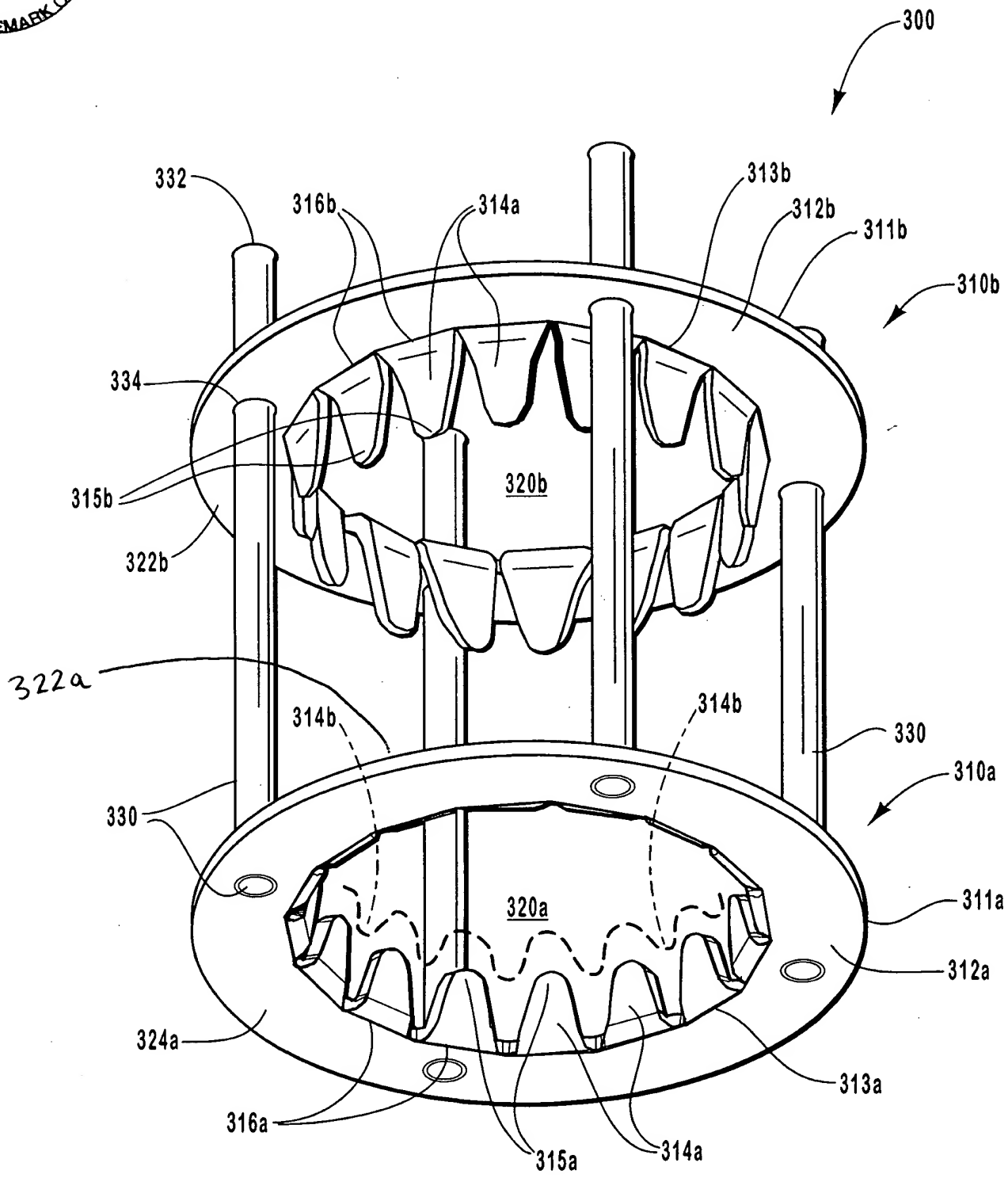

FIG. 3A

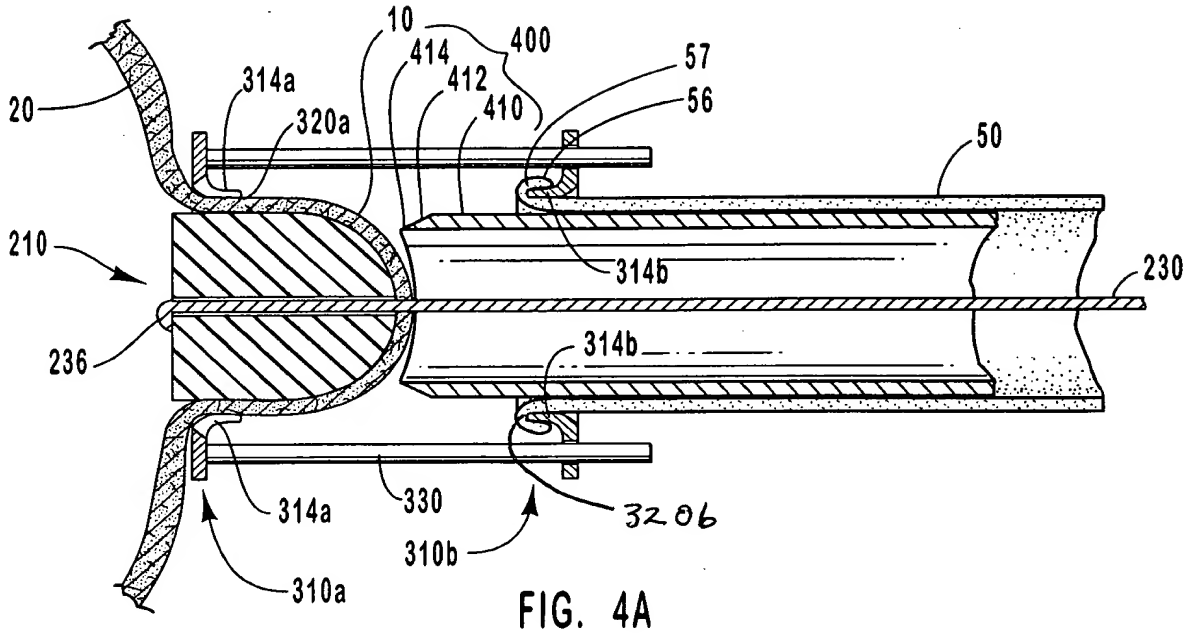

FIG. 4A

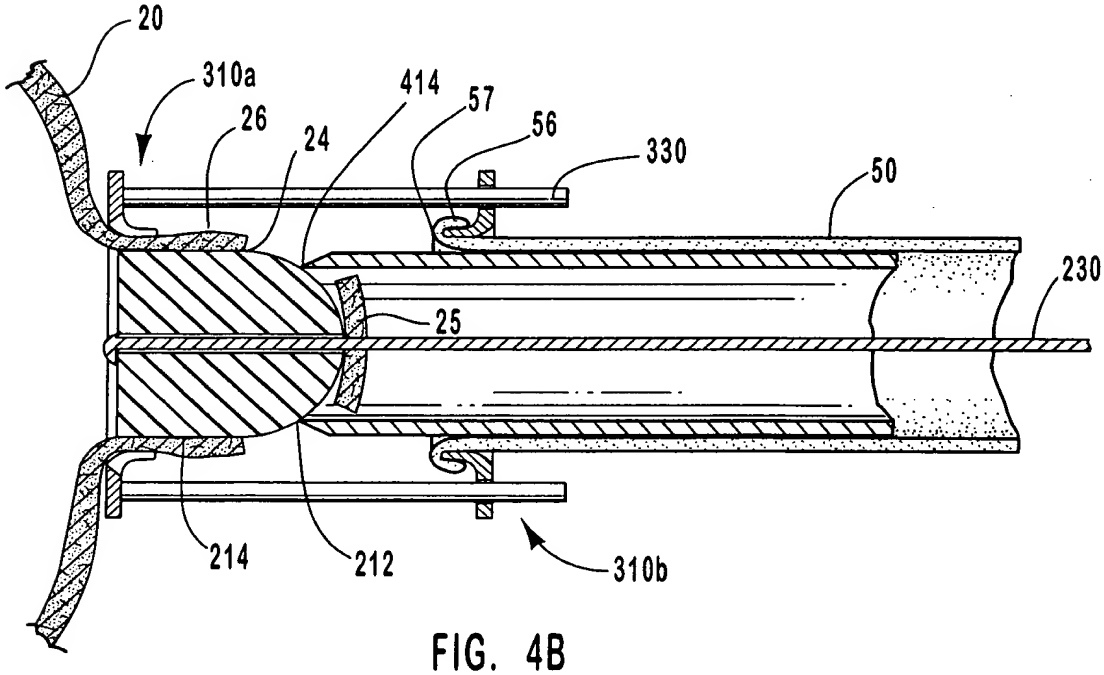

FIG. 4B

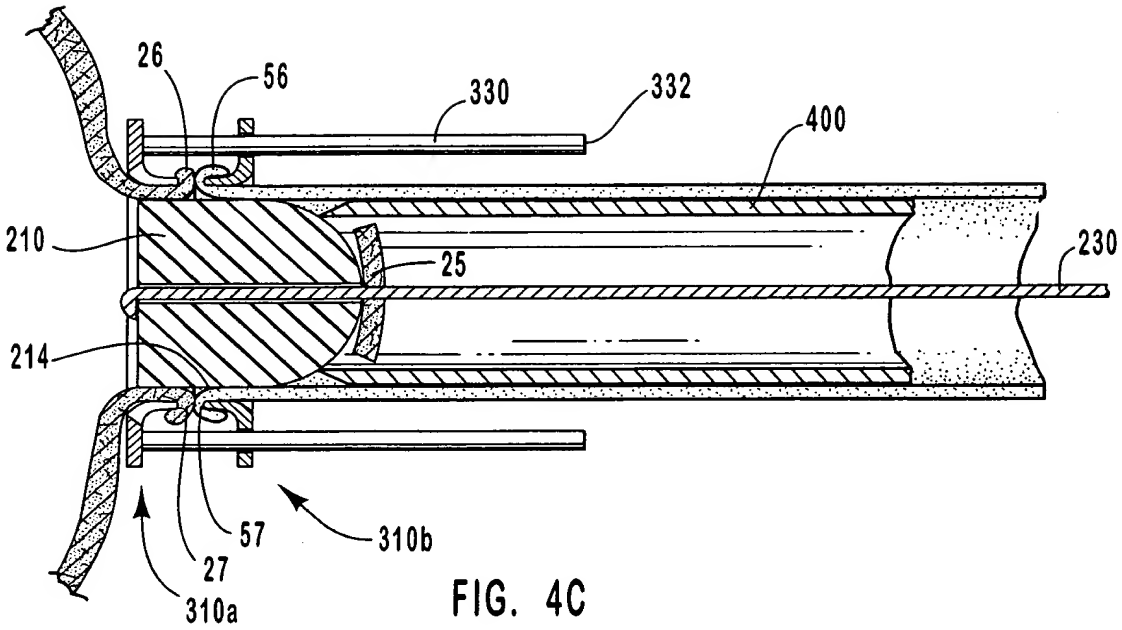

FIG. 4C

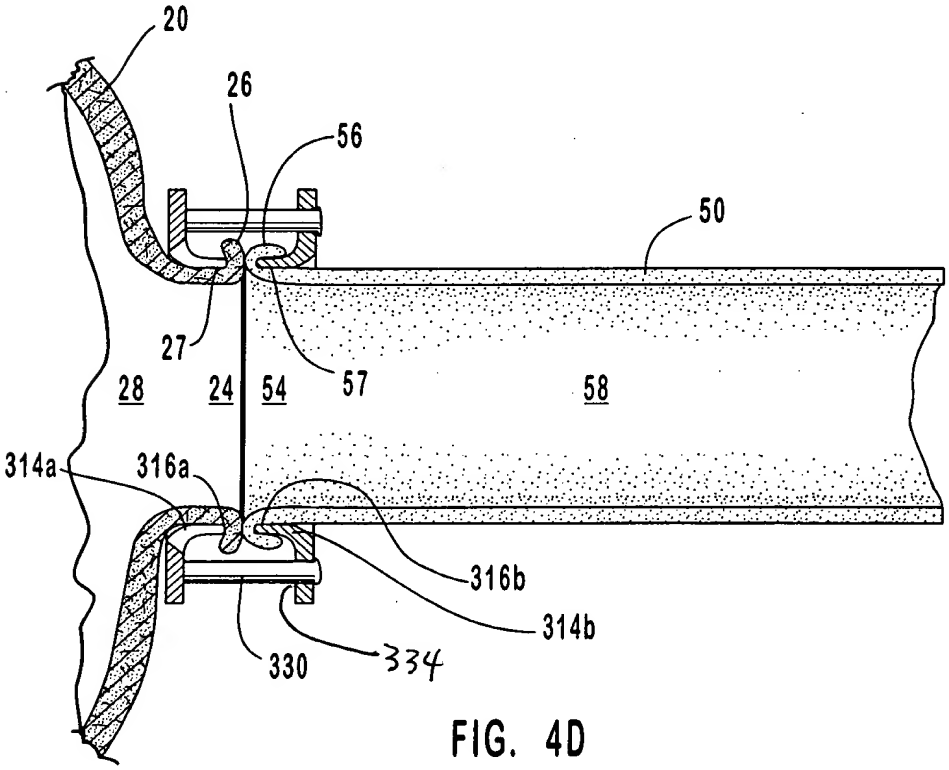

FIG. 4D

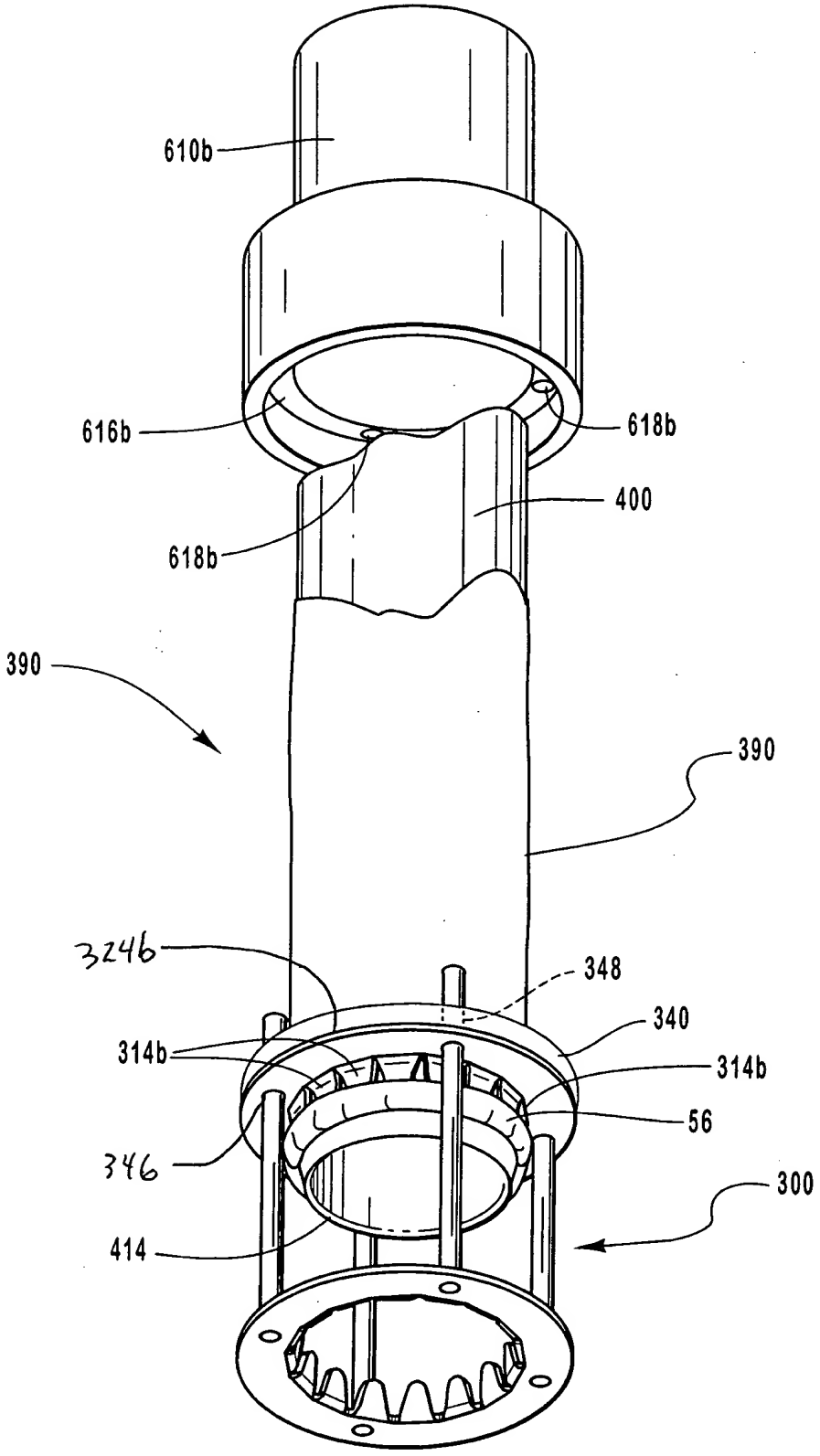

FIG. 5A

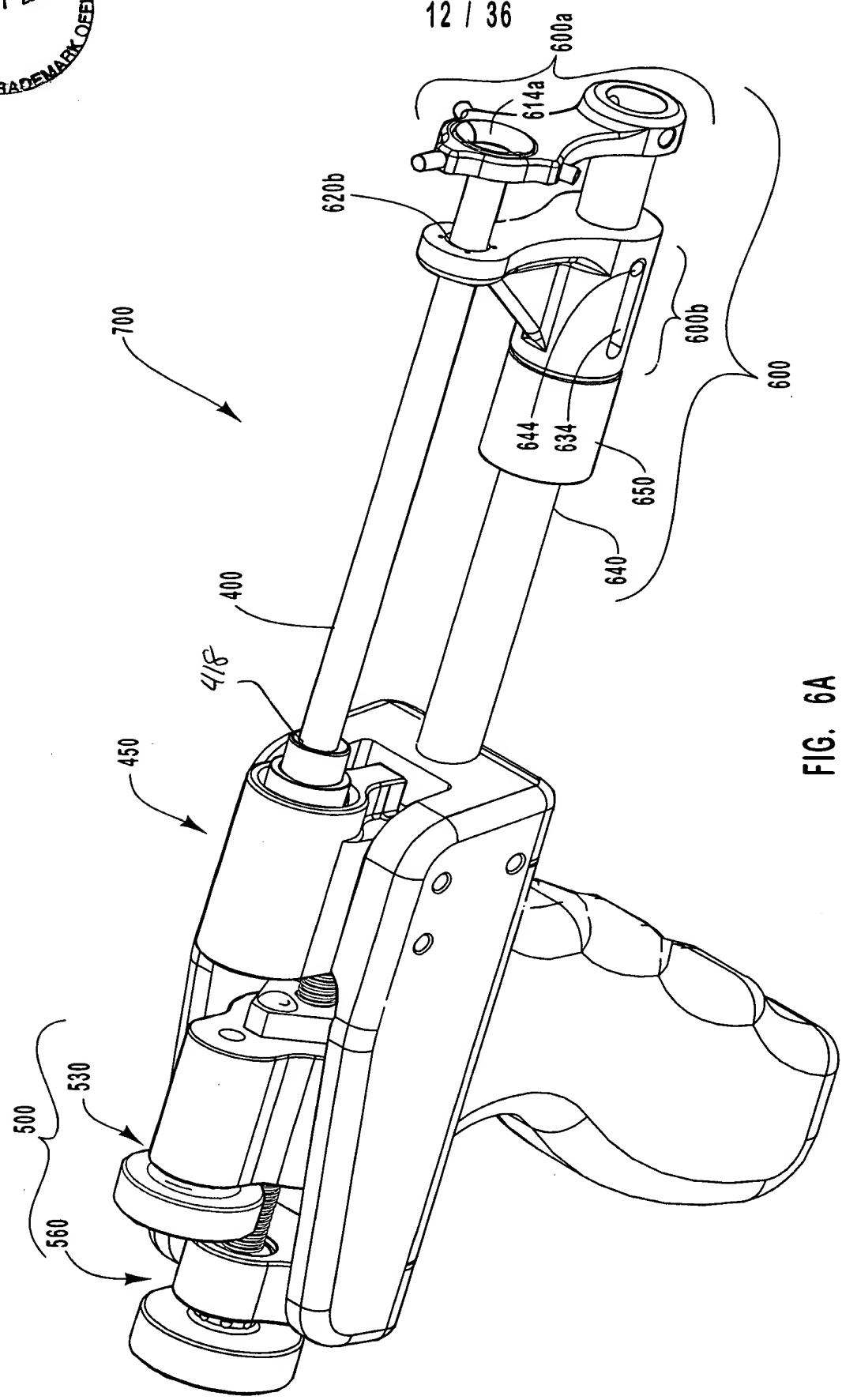

FIG. 6A

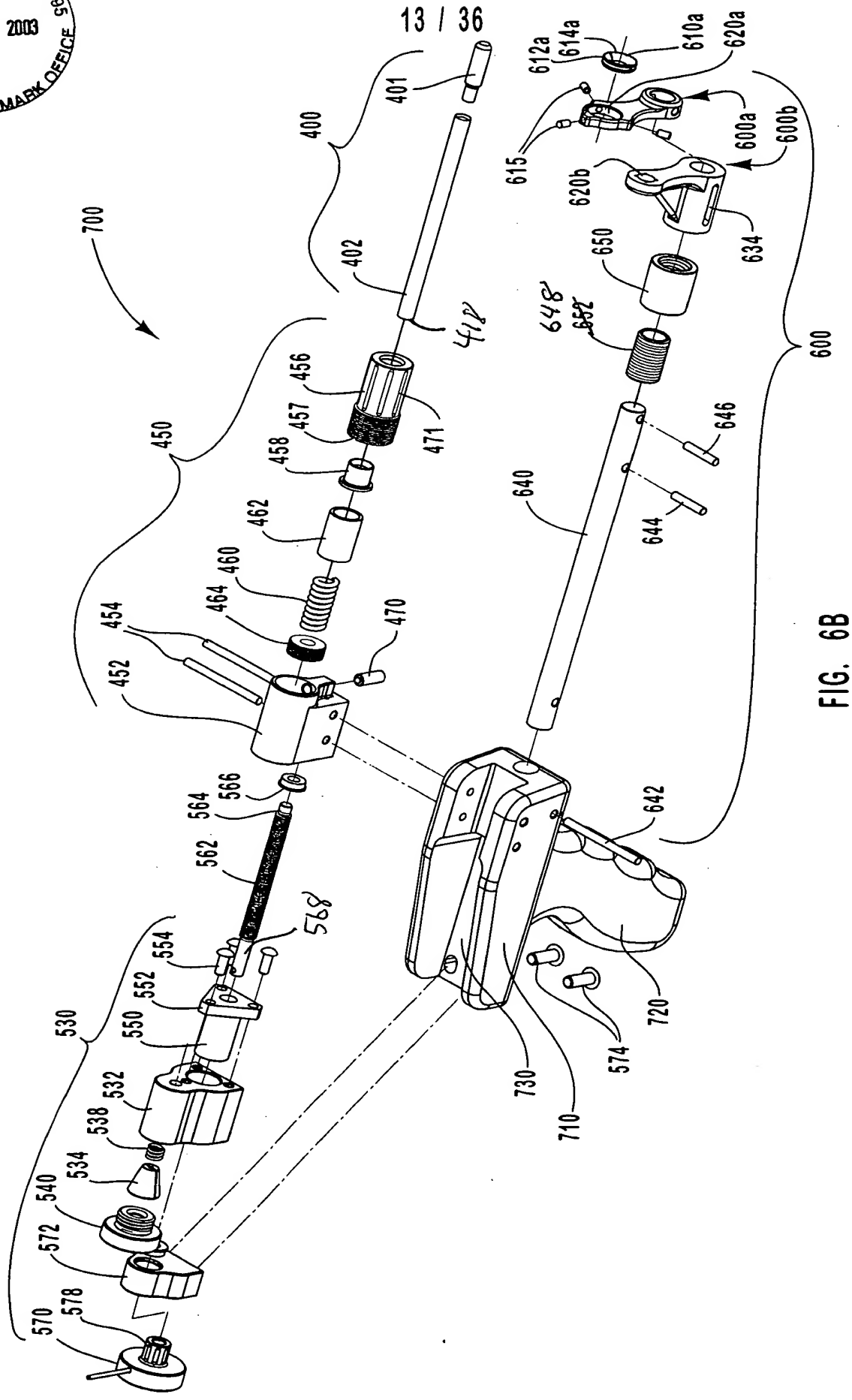

FIG. 6B

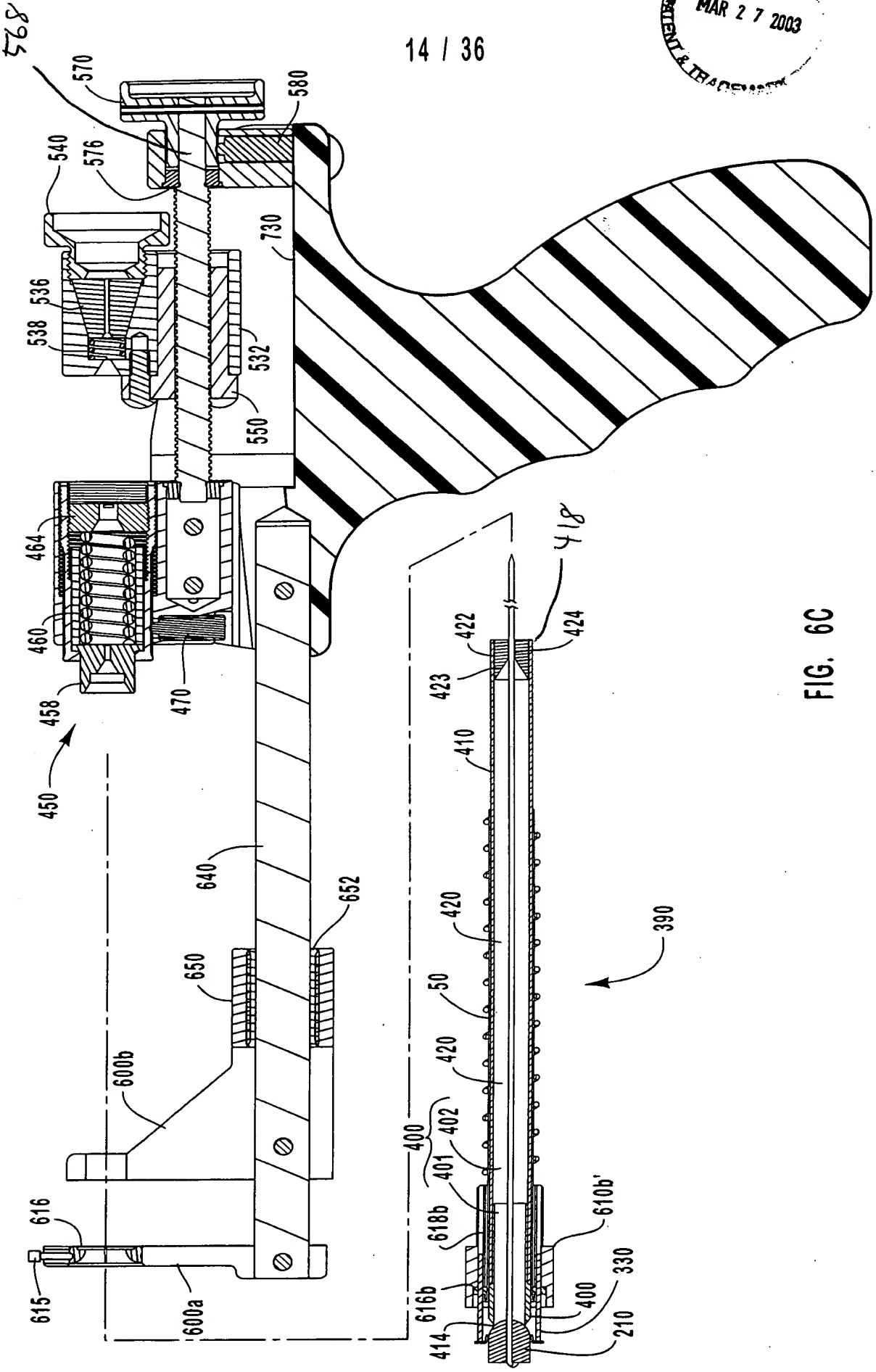

FIG. 6C

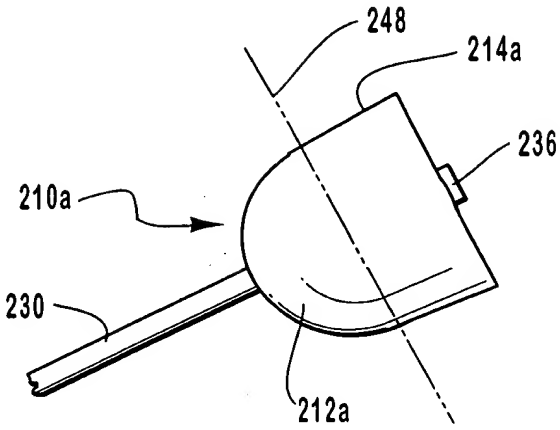

FIG. 7A

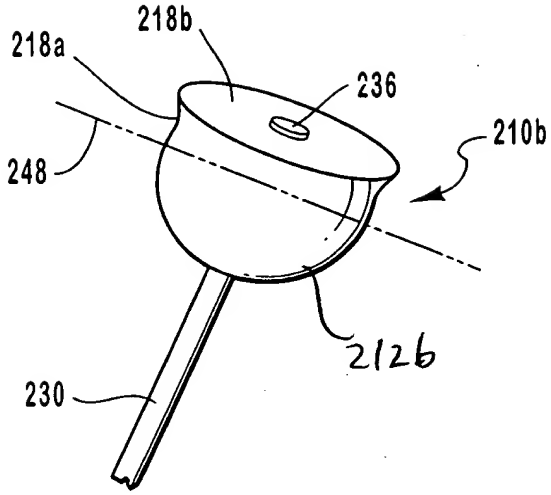

FIG. 7B

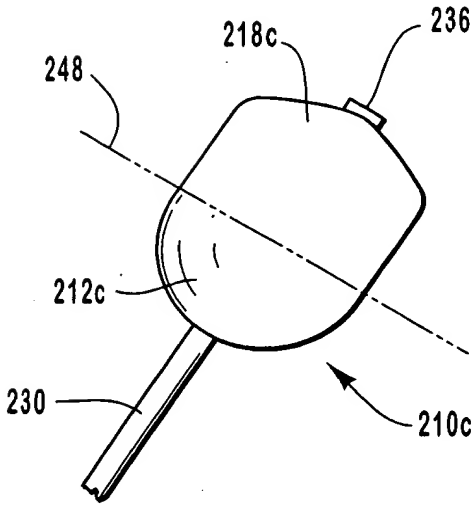

FIG. 7C

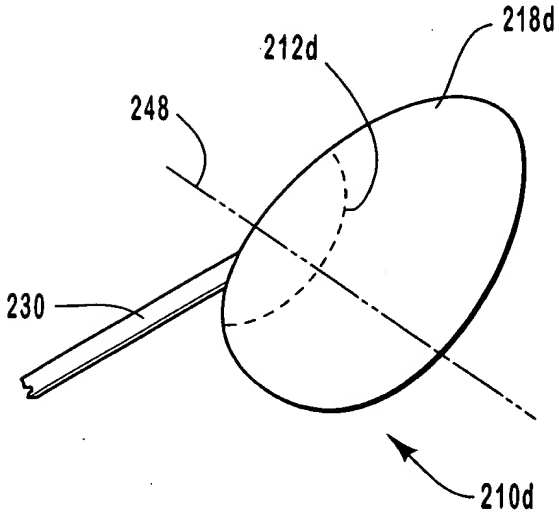

FIG. 7D

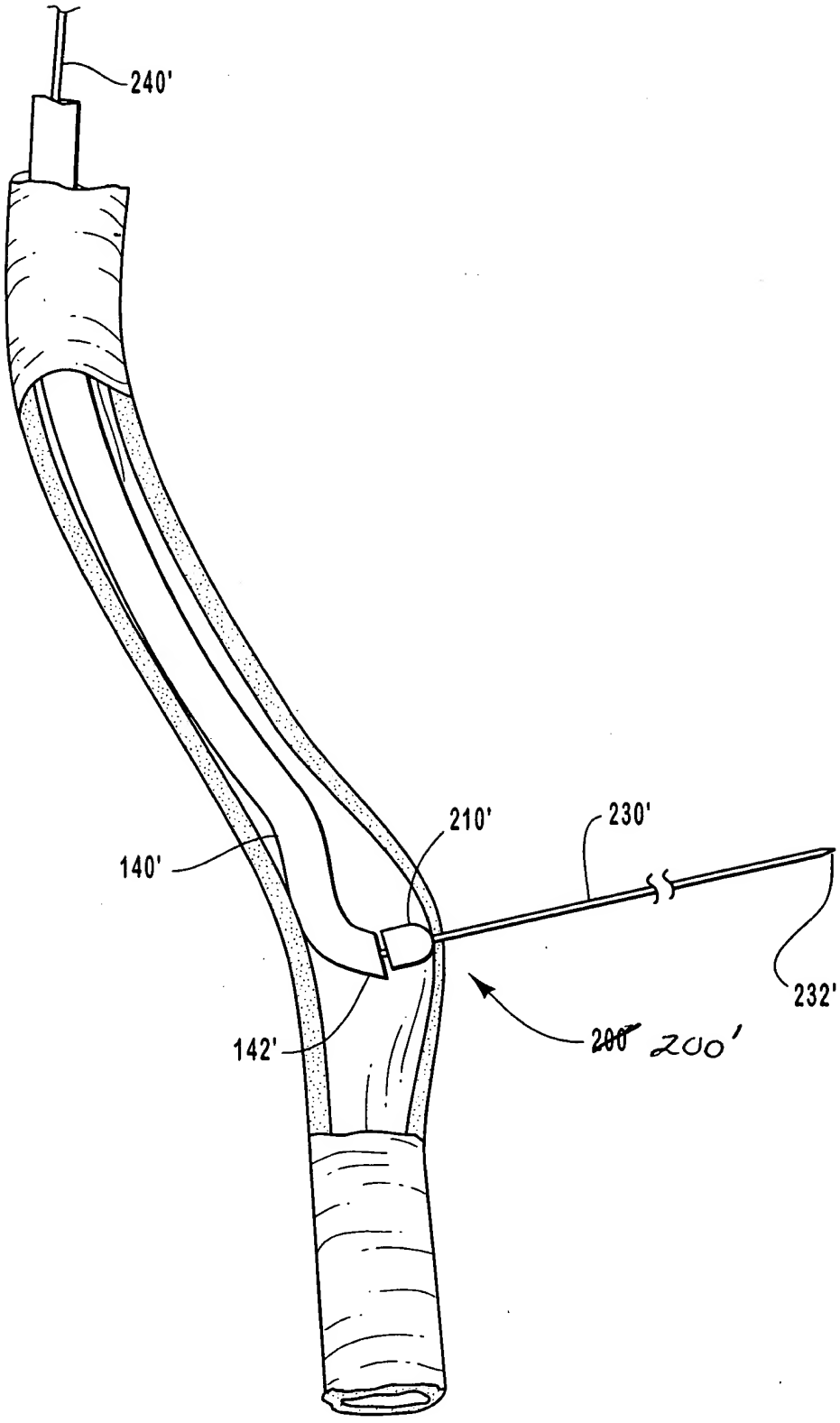

FIG. 8

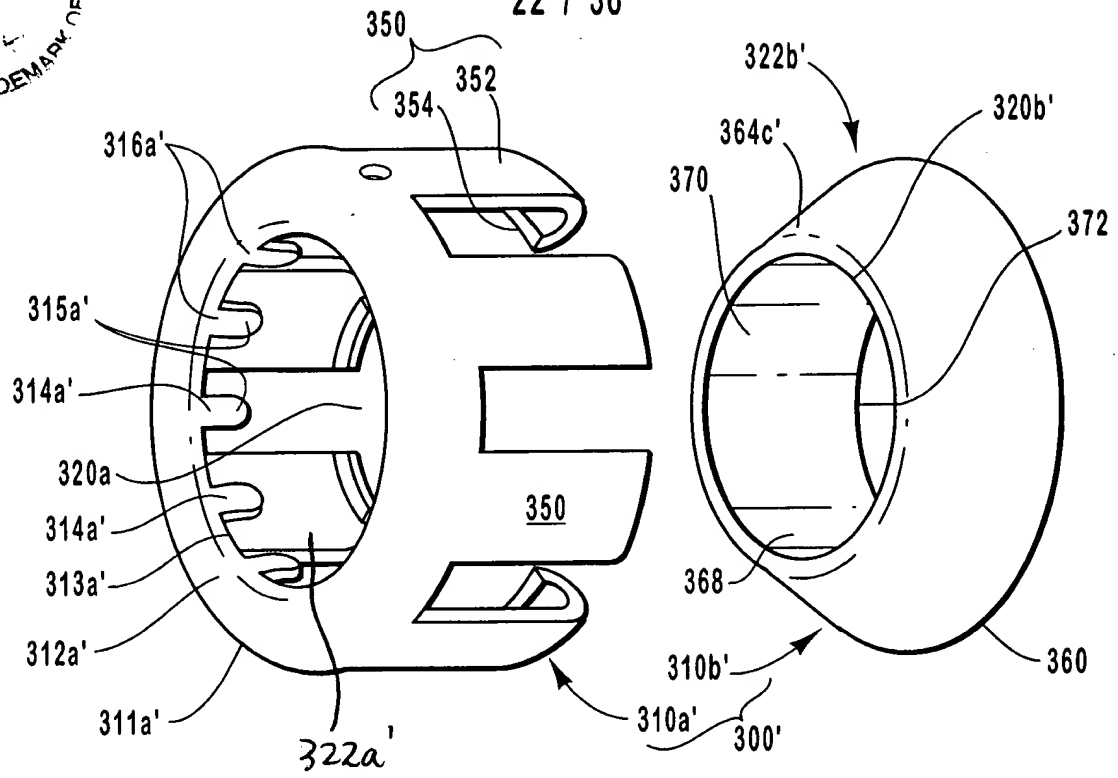

FIG. 12A

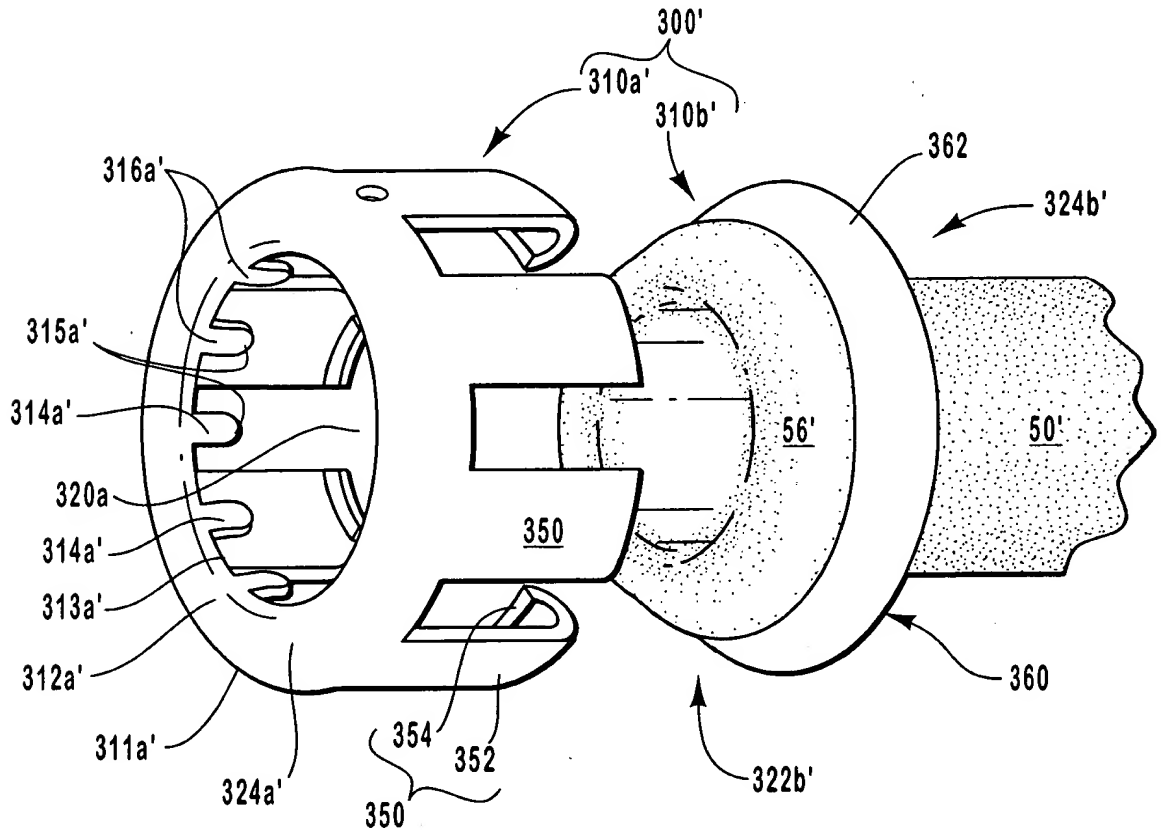

FIG. 12B

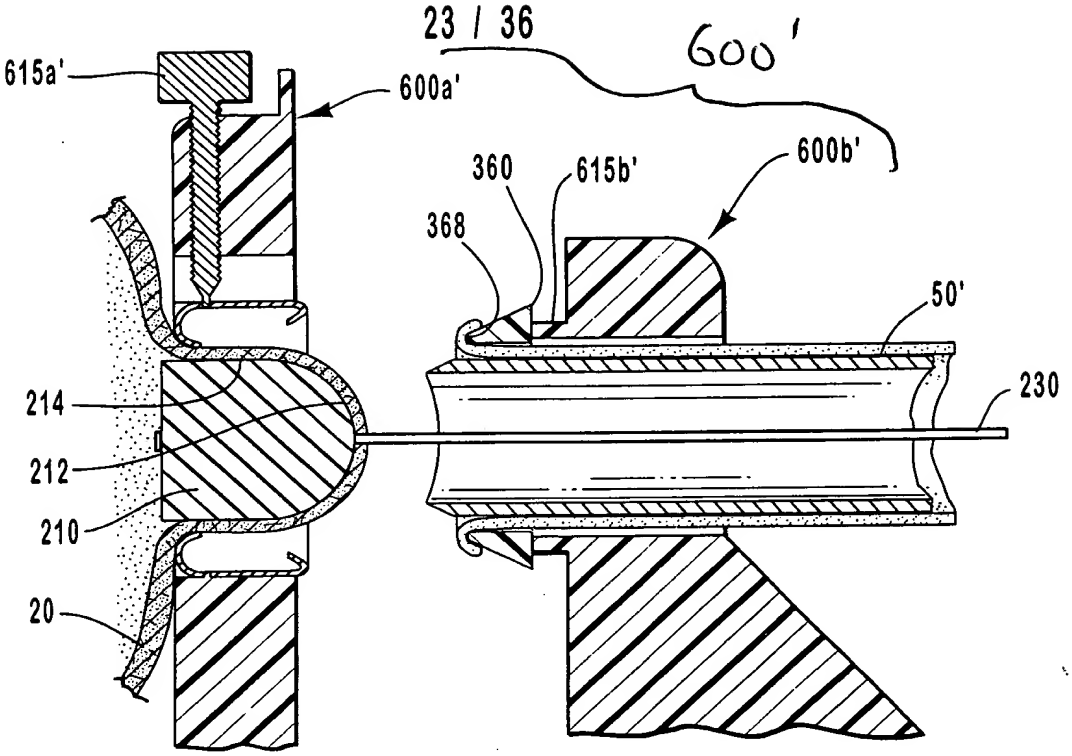

FIG. 12C

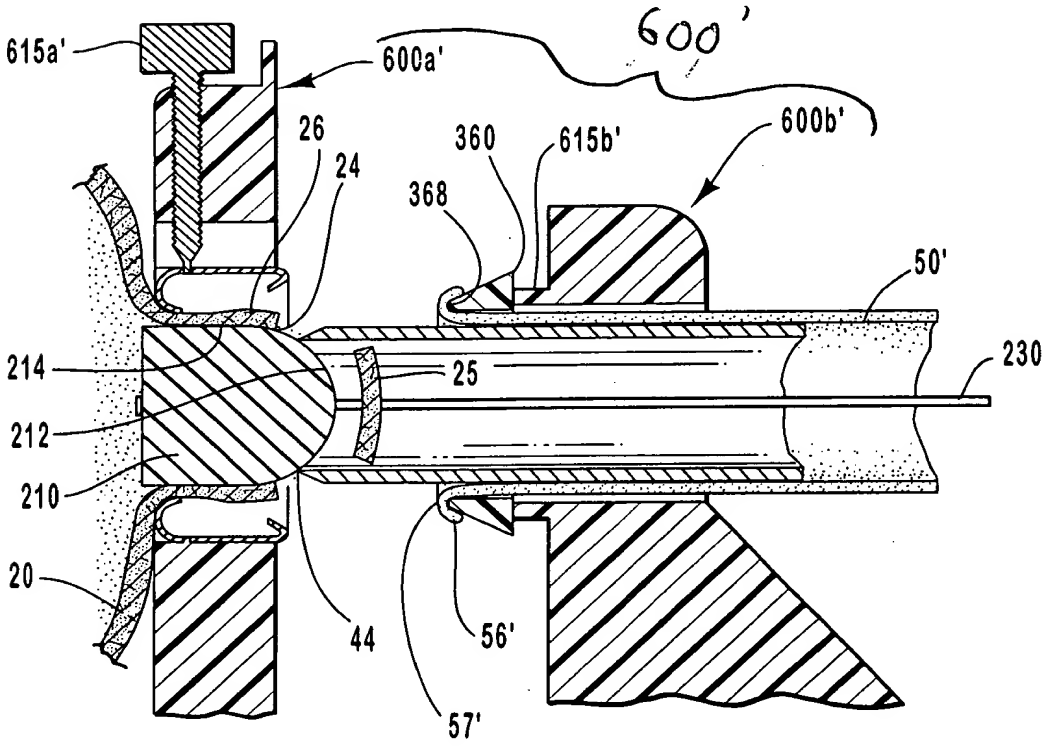

FIG. 12D

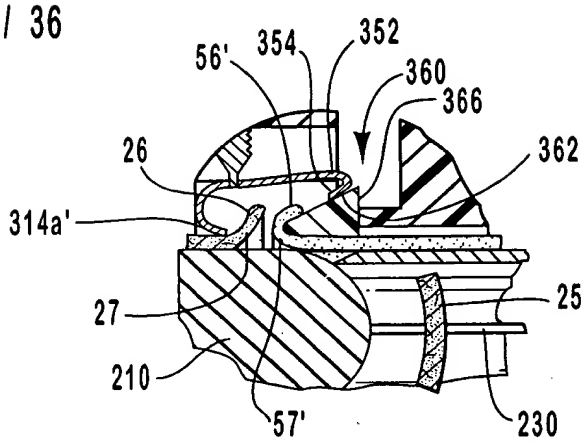

FIG. 12E

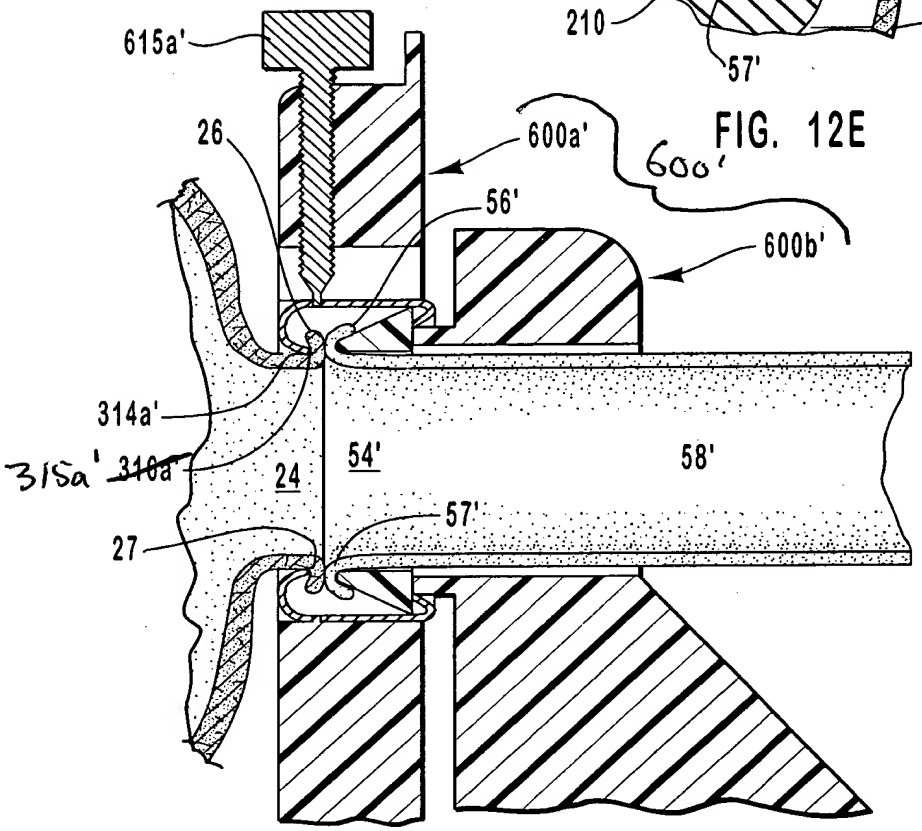

FIG. 12F

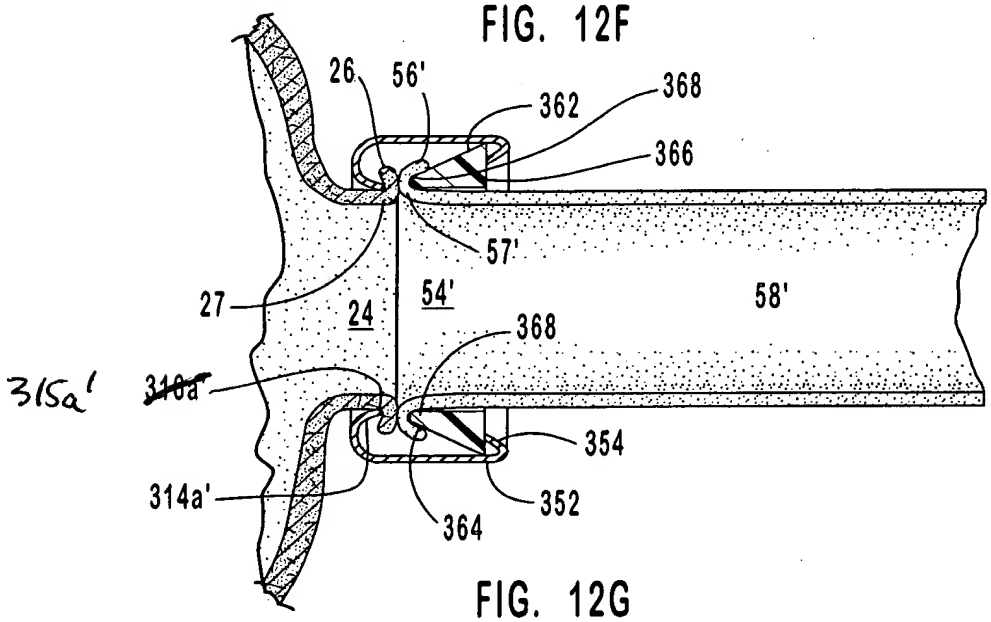

FIG. 12G

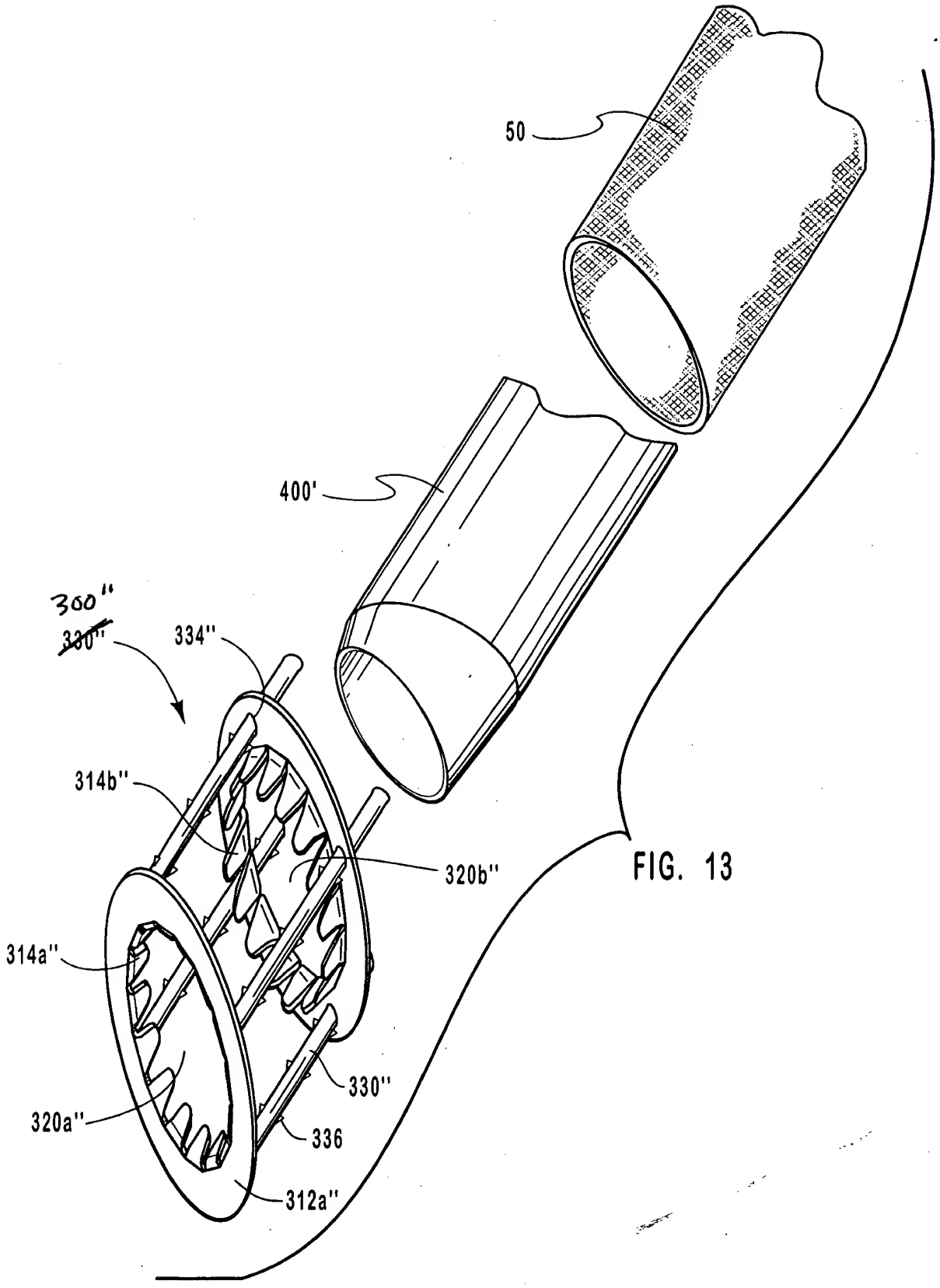

FIG. 13